

Medical Practice Guidelines

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Prescriptive standards of clinical conduct—practice guidelines—have proliferated throughout medicine over the past decade. Practicing physicians are confronted with a plethora of guidelines developed for different purposes by a diverse body of public and private organizations. We review factors contributing to the growth of guidelines, their desirable features, and consequences, legal and otherwise, of implementing guidelines. Few studies have examined whether, and under what conditions, guidelines are effective in changing physicians' practices and patients' health. Nonetheless, expectations for guidelines remain high because they are one of the only instruments of health care reform that promises to improve the quality of care while reducing overall health care costs. Efforts to develop guidelines are likely to continue unabated for the foreseeable future. Additional research comparing different methods of developing and disseminating guidelines is needed.

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Practice guidelines have been used for half a century to facilitate effective decision-making by physicians.¹ The number of organizations developing guidelines has increased substantially in recent years. In 1990, there were 26 physician organizations responsible for creating more than 700 guidelines.² By 1992, these figures had risen to 45 and 1,500, respectively.³ Many observers regard the proliferation of guidelines as part of "a significant cultural shift, a move away from unexamined reliance on professional judgment toward more structured support for, and accountability of, such judgment."^{4(p2857)} Contemporary debate is focused on the role guidelines can and should play in health care reform.

Definitions of practice guidelines are proffered by a number of different organizations.⁵⁻⁷ The Institute of Medicine describes guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."^{8(p38)} Guidelines developed by the American Academy of Ophthalmology are referred to as "preferred practice patterns . . . because no two patients' needs are ever identical [and] 'cook book' medicine cannot ensure quality."^{9(p67)} The American Medical Association refers to "practice parameters," emphasizing the view that guidelines must be flexible and allow for individualized treatment planning.² Perhaps the most straightforward definition is that developed by Shapiro and co-workers, who define guidelines as "statements of approaches to care for particular clinical situations."^{10(p233)}

Although guidelines can take many forms, most defi-

nitions emphasize their common aim of improving physician decision-making by detailing appropriate indications for specific medical interventions. Implicit in most definitions is the notion that physicians should be allowed flexibility in responding to the particular circumstances of each patient. Eddy distinguishes between practice standards, which must be followed in nearly all cases, and practice guidelines, which permit greater flexibility.¹¹ According to Eddy, practice guidelines can be formulated when some important health results of an intervention are known, whereas practice standards require greater knowledge of the health and economic consequences of an intervention. To date, few practice standards have been developed and most guidelines do not incorporate cost considerations.

Developing Guidelines

The federal government is increasingly involved in developing guidelines. The principal mandate of the Forum for Quality and Effectiveness in Health Care, the office within the Agency for Health Care Policy and Research responsible for developing guidelines, is to develop, review, and update clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.^{12(p6)}

Medical specialty societies have taken a leading role in developing guidelines. The Council of Medical Spe-

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cialty Societies and the American College of Physicians are strong proponents.¹³ Other groups directly involved in developing guidelines include hospitals and health maintenance organizations, insurance, managed care, and utilization review companies, insurance carriers, voluntary organizations such as the American Cancer Society, and research centers, such as the Rand Corporation, the Academic Medical Center Consortium, and the Institute of Medicine.^{1,14,15}

A number of other organizations support practice guidelines development. The Joint Commission on the Accreditation of Health Care Organizations asked medical specialty societies to make guidelines development a priority,¹⁶ as have groups representing employer perspectives on health care issues.¹⁷ Some states have promoted the development of statutorily imposed guidelines as a means of implementing malpractice reform.¹⁸

Guidelines are one of the few tools that can be used to control the volume and intensity of services offered to patients without sacrificing quality.¹⁰ Thus, it is likely that federal involvement in guidelines development through agencies of the US Public Health Service such as the Food and Drug Administration, National Institutes of Health, Centers for Disease Control and Prevention, the Health Care Financing Administration, US Preventive Services Task Force, and the Congressional Office of Technology Assessment, will continue apace.

States have not been as active as the federal government in developing guidelines. The number of guidelines developed at the state level may increase in coming years, however, to the degree that health care reform occurs at the state rather than the federal level. Efforts to link practice guidelines and protection from malpractice liability in Maine are described later in the article.

Guidelines developed by private organizations, including those created by professional medical societies, are likely to increase in number. A recent General Accounting Office survey found that the two most common reasons for developing guidelines reported by 27 medical societies were improving quality of care and defending against external pressures such as malpractice litigation or conflicting guidelines for care established by other organizations.¹⁹

Factors Contributing to the Growth of Guidelines

Medical guidelines have proliferated over the past decade. Before 1980, eight medical societies had developed guidelines. Currently, more than 50 physician organizations are developing guidelines.⁷ Medical specialty societies published more guidelines between 1990 and 1992 (800+) than they had before 1990.³

Investigations reporting high levels of inappropriate medical care are an important impetus to the development of guidelines. Nearly every study that has looked for the overuse of medical services has found it.²⁰ Many medical procedures are done at widely varying rates in different geographic areas.²¹⁻²³ Practice variation is assumed to imply an overuse of medical procedures in some geographic

regions. The overuse of medical procedures, in turn, is attributed to physicians' uncertainty regarding appropriate indications for particular procedures. Contemporary observers maintain that physicians' uncertainty has increased because medical information is accruing at an unprecedented rate.²⁰ The rapid development of medical technologies and the fact that technologies are less concentrated also contribute to practice variation. Current practice trends are such that many patients are treated by physicians who are relatively inexperienced in applying certain treatment procedures. For example, the modal number of carotid endarterectomies done by surgeons attempting the procedure is one per year.²⁰

Advocates of practice guidelines contend that they decrease physician uncertainty and reduce rates of inappropriate care by codifying knowledge in particular practice areas. They provide physicians with information in a form that is easy to use. A recent survey found that physicians wanted medical information in a form that is concise and directive.²⁴ Leape noted that "there is poor dissemination of clinically relevant information in a form that is useful to the practicing physician."^{25(p43)}

Desirable Features of Guidelines

Although there was general agreement on the desirability of practice guidelines in 1990, Berman and Kaegi observed that greater attention to the processes by which guidelines were developed and disseminated was needed.¹⁶ By 1992 Kaegi argued that the important questions had changed from who should develop practice guidelines and how should they be developed to what are the effects of practice guidelines on practitioner behaviors and patient outcomes and do practice guidelines increase treatment cost-effectiveness.²⁶

Desirable characteristics of guidelines and reliable methodologies for implementing them have been identified. Most observers agree that guidelines should be widely disseminated,³ based on a methodology open to public scrutiny,²⁷ revised regularly and in response to relevant scientific advances,²⁸ and derived from scientific evidence of the highest quality.¹² Leape suggests that guidelines should be comprehensive, including all indications for a procedure; specific, clearly describing conditions under which a treatment is recommended; inclusive, incorporating all factors that should be considered before recommending a procedure; and manageable, easy to understand and practice.²⁵ The Institute of Medicine suggests that guidelines should have validity—they should lead to the health and cost outcomes projected for them—clarity, clinical flexibility and applicability, and reliability and should be developed by a multidisciplinary process that includes participation by representatives of key affected groups.^{8,19}

Contemporary protocols for developing guidelines have many common features:

- Reviews of extant research findings are conducted, often with the aid of the National Library of Medicine.
- Studies are selected according to predetermined cri-

teria and findings are summarized using techniques such as meta-analysis.

- Panels of experts are convened and guidelines are revised according to feedback received.
- Consensus is achieved in some areas and areas where disagreement or uncertainty remains and more research is needed are noted.

Although basic agreement has been achieved regarding the qualities practice guidelines should possess, relatively few investigations have assessed their effectiveness.

Do Guidelines Work?

Efforts to develop guidelines at the national level are frequently unsuccessful in changing physicians' practices, often because of the failure to adequately disseminate guidelines to target groups of practitioners.

A study done in Italy assessed whether a national education program based on a dissemination of practice guidelines for breast, colorectal, and ovarian cancer would affect physicians' knowledge, acceptance, and implementation of guidelines.²⁹ Guidelines were disseminated through booklets distributed to all general hospitals and at national scientific meetings. Physician concurrence with guidelines recommendations was unsatisfactory, and compliance with practice guidelines was highly variable. Evaluations of the National Institutes of Health Consensus Development Program reach similarly discouraging conclusions.³⁰ Medical care was examined before and after practice guidelines were introduced that addressed the surgical management of primary breast cancer, using steroid receptors in breast cancer treatment, cesarean childbirth, and coronary artery bypass surgical procedures. Guidelines were widely published in the lay and professional presses. Although moderate success was achieved in disseminating guidelines to appropriate target audiences, conference recommendations largely failed to change physicians' practices. The authors noted that it is notoriously difficult to change physicians' behaviors merely by providing information. They suggested that engaging the "active participation of the target audience in defining and disseminating the message" might be an effective diffusion strategy.^{30(p822)}

The effects of distributing to obstetricians in Canada a consensus statement designed to reduce the incidence of cesarean sections among women with a previous cesarean section were assessed.³¹ Questionnaires administered before and two years after the dissemination of guidelines indicated that obstetricians' knowledge of the content of the guidelines was poor and that their practices had changed little.

Guidelines developed by national organizations can affect the behavior of physicians if there are incentives encouraging their use. Guidelines adopted in 1984 by the American College of Cardiology detailing appropriate indications for pacemaker implantation were included in Medicare coverage policy and were widely accepted by physicians. These guidelines resulted in the more appropriate use of cardiac pacemakers and in notable reductions in the use of pacemakers in Medicare patients.²

Anesthesiologists agreeing to adopt intraoperative monitoring guidelines developed by the American Society of Anesthesiologists in 1986 were offered a 20% premium reduction for liability insurance in 1987 by the Massachusetts Medical Malpractice Joint Underwriters Association. Before this agreement, anesthesiologists in Massachusetts averaged a total of six hypoxic events annually. Between 1987 and 1990, the insurance carrier registered no lawsuits related to hypoxia injury among physicians who followed the guidelines.³²

Practice guidelines developed locally, or adapted to local conditions, are generally more effective than national guidelines disseminated to localities without consideration of their specific circumstances. Durand-Zaleski examined whether guidelines for treating hypovolemia could be successfully implemented in a 1,000-bed hospital.¹⁵ Guidelines were aimed at reducing the use of albumin in favor of less costly treatments and were distributed to all physicians at the hospital, with meetings conducted for physicians from departments primarily concerned with treating hypovolemia. Monthly reports of the amount of albumin prescribed and its cost were provided to each physician. Implementing these guidelines was associated with a 40% reduction in albumin use in the following year. Implementing guidelines successfully was attributed to the intensity of dissemination, which included publishing guidelines in medical journals, direct mailings of guidelines to physicians, meetings, and the use of local physician opinion leaders.

The effects of status asthmaticus treatment guidelines on pediatric outcomes and pediatricians' behaviors within a large health maintenance organization were examined.³³ The recommendations of a national panel of experts served as the basis for the draft guidelines. Key personnel from several disciplines reviewed the guidelines and assisted in revising them. Guidelines development activities exerted positive effects: "The consensus process raised important issues and alerted the clinical staff to alternative practices as well as the latest recommendations in the management of acute asthma."^{33(p472)} Comparisons between patients treated before and after guidelines were implemented found better results in patients treated under the new guidelines and important changes in pediatricians' behaviors. The authors of the report argue that local participation in guidelines development may move care closer to standards set by national panels of experts.

Guidelines for patients admitted to intensive care units were developed in 1990.³⁴ Draft guidelines were mailed to directors of intensive and coronary care units throughout Massachusetts, a meeting with these directors was convened to refine the guidelines, and statewide consensus on practice guidelines was achieved. For six months, a staff cardiologist reviewed the use of all intensive care unit beds daily to assess patients' need for continued intensive care unit care. This resulted in considerable reductions in the mean length of hospital stay and mean intensive care unit length of stay, relative to the baseline condition. Mortality and readmission rates were also reduced.

TABLE 1.—Potential Effects of Practice Guidelines

Positive Effects	Negative Effects
Help patients make informed health care decisions	May lead to "cookbook medicine"
Help physicians use appropriate health care technologies and reduce inappropriate care	May stifle innovative medical practice and the application of new technologies, particularly if guidelines are made the standard of care
Assist physicians in making cost-effective health care decisions	May increase medical costs by identifying interventions that are underused
Assist third-party payers in utilization review, performance rating, and reimbursement decisions	Cost reductions may not be substantial and may not outweigh costs of developing and updating guidelines
Serve as the basis for developing clinical indicators used to assess organizational competence and identify aberrant practitioners	May reduce research activity in areas where guidelines are developed
Could be used by physicians and organizations to improve practice	May contribute to disinterest in medicine as a career, quality of physicians may decline
May lower malpractice litigation costs by improving quality of care and serving as an "affirmative defense" in malpractice litigation	May provide inculpatory evidence in malpractice cases or increase malpractice litigation and costs or both
Medical textbooks and other educational materials could be organized around guidelines	

Several preliminary conclusions can be drawn from studies evaluating the effectiveness of guidelines in changing the behaviors of clinicians. Merely disseminating guidelines is not effective. Instead, incentives, such as reduced malpractice insurance premiums, should be offered to physicians to encourage them to use guidelines. Physicians or their representatives actively participating in the development process and local adaptation of national guidelines are potentially fruitful approaches. Using physician opinion leaders and physician profiling has proved effective in some studies.^{34,35} In general, the more intense and diverse the dissemination and the more physician involvement, the more likely it is that physicians will be aware of guidelines and apply them in practice. Are some methods of developing guidelines particularly effective in shaping practitioners' behaviors? A recent Institute of Medicine report notes that, "As the guidelines development process evolves, more attention is being paid to who takes part in the process, when and how they participate, and what such participation should achieve."^{19(p170)} Different methods of creating guidelines panels, selecting panel members, and identifying reviewers of draft guidelines should be compared. A particularly important issue is determining how patient preferences should be incorporated into developing guidelines. Research is needed on the following:

- What are the best techniques for eliciting patient preferences?
- What information and other conditions are required for informed and rational statements of preference?
- What are the technical and policy issues in quantifying individual preferences (utilities) and aggregating preferences for purposes of making judgments about what care is appropriate?^{19(p181)}

Possible Consequences of Practice Guidelines

Some analysts contend that guidelines deleteriously affect the practice of medicine. Appelbaum questions whether guidelines codify knowledge in a way that stifles innovative medical practice.³⁶ Others argue that continu-

ing investigation in a practice domain is undermined by the perception of agreement among expert panelists developing guidelines in that area.³⁰ "Cookbook medicine" may contribute to a disinterest in medicine as a career and the quality of new physicians may decline as the practice of medicine becomes increasingly perfunctory.

Legal implications of guidelines are the focus of several recent reports.^{37,38} Bulger considers the possible liability of developers and users of guidelines, the respective roles of federal and state governments in institutionalizing guidelines, and the effect of guidelines on medical malpractice and decision-making, emerging issues of importance.³⁹ Many physicians are concerned that guidelines can provide inculpatory evidence that will be used against them in court as well as evidence that is exculpatory.⁴⁰

The Maine Medical Liability demonstration project was established by the state legislature in an attempt to reduce the practice of defensive medicine by allowing physicians to use adherence to guidelines as a defense in malpractice cases. Special advisory committees from four medical specialties adapted national guidelines for local use. Guidelines were subsequently placed into law. Physicians agreeing to follow the guidelines—more than 50% in each specialty—are allowed to use adherence to the guidelines as an "affirmative defense" in malpractice litigation. The affirmative defense is intended to be raised early in the litigation process as it forestalls, if successful, lengthy hearings based on the merits of the case. Adherence to established guidelines can be raised by the physician-defendant in tort liability cases but cannot be used by the plaintiff. Data on the number of malpractice claims filed are not yet sufficient to evaluate whether the Maine project reduces malpractice litigation. Recent indications are that Vermont, Florida, and Minnesota may be developing similar programs.

Medical review organizations, and the physicians employed by them, may be vulnerable to malpractice suits if their actions are not in the best interests of patients. The Institute of Medicine recently cautioned that "prudence dictates that those applying them [practice guidelines] in medical review programs should expect to be held legally

accountable for their actions and should manage their affairs accordingly.”^{19(p118)}

One recent case involved a patient discharged from hospital on the basis of a recommendation derived from a clinical algorithm developed by the California Medicaid program (Medi-Cal), despite a physician's request for a few days of additional treatment. The patient, in whom complications later developed, sued Medi-Cal for negligence for requiring her physician to discharge her against his better judgment. The court observed that Medi-Cal and others who develop guidelines could be held liable for negligence resulting from the application of guidelines under some conditions and that physicians following review guidelines were liable to the extent that they did not exercise good medical judgment.³⁸

Another important issue is whether guidelines should be used as the standard of care or simply as evidence of the standard of care. The American Medical Association and the Institute of Medicine support the use of guidelines as evidence of the standard of care, in preference to their use as mandatory standards, in malpractice cases.^{19,41} Additional concerns are that mandatory guidelines could diminish the innovative practice of medicine and the application of new medical technologies. Table 1 outlines the possible positive and negative effects of practice guidelines.

Discussion

Expectations for guidelines remain high despite a paucity of data supporting their efficacy.⁴² Few studies examining the relationship between methods of developing and disseminating guidelines and their effects on physicians' practices and patients' outcomes have been reported. Interest in guidelines remains strong, however, because “purely financial approaches to health care cost-control run the risk of decreasing spending on appropriate, as well as inappropriate services.”^{10(p222)} Proponents contend that well-designed guidelines will increase quality and reduce net costs of health care, but little is known regarding their potential to reduce overall health care costs.

Adverse consequences of implementing guidelines have not been adequately assessed. In particular, the contention that guidelines will discourage physicians from applying new technologies and interventions that are appropriate to an individual patient but absent from the relevant guidelines should be empirically evaluated. It is also important to assess whether the development of guidelines will be able to keep pace with rapidly changing areas of medicine. Additional experience with guidelines and more research are needed before their manifold effects can be predicted with accuracy.

Guideline development in the 1990s is likely to continue unabated in both the public and private sectors as pressures mount to contain costs and improve the quality of care. Guidelines will undoubtedly play some role in health care reform, although the precise nature of that role is currently a matter of speculation. Many experts caution that guidelines are not a panacea for all that ails the health care system. Considerably more research is needed before the full potential of clinical guidelines can be realized.

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CHRONIC CONDITION

Two failures.
Then a third.
A fuss of tubes.

After the doctor is called,
he disappears
between my legs.

The catheter's
rubber lip
inserted into me

inch by inch
burns,
an unrelenting pressure,

the tip pushed
deeper and deeper
until it enters,

the bladder's crypt
opening
for this thief

who picks the lock
of my privacy
and smiles,

not noticing
my voice
change pitch

panic
chasing across the years
to find a child

crouched on the floor,
something pulled
from a drawer,

a baffled scream,
nothing more.
Blood drains from my face

as I rush back to the place
where my body stops
being part of me,

and I look down
over myself
at a stranger's legs

being stretched apart.
When it's over
I put on my clothes

no longer a girl.
The moon's untouchable scar
hovers

outside my window.
I can barely follow
the doctor's anesthetic words

the bandage he offers,
all the treatments
he has not tried.

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